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EXAMINER

NEGIN, RUSSELL SCOTT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,811	<b>Applicant(s)</b> LERMAN ET AL.	
	<b>Examiner</b> RUSSELL S. NEGIN	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 21-23, 33-35 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-20, 24-32 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/16/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Species A and E in the reply filed on 10 December 2008 is acknowledged.

Claims 9-11, 21-23, 33-35, and 40-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10 December 2008.

Accordingly, claims 1-42 are pending and claims 1-8, 12-20, 24-32, and 36-39 are examined in the instant application.

### *Oath/Declaration*

The declaration filed on 16 May 2006 is defective because all of the copies of the declaration do not list each inventor. In this case, there is only one COMPLETE copy of the declaration with an extra (i.e. an additional) page 3's. The "first" page 3 lists inventors Lerman and McQuown and is signed by McQuown. The "second" page 3 also lists inventors Lerman and McQuown and is signed by Lerman. Page 4 lists inventor Mishra and is signed by Mishra. Consequently, it is unclear as to which copy of page 3 is part of the "original" oath which acknowledges Mishra as an inventor. See MPEP 201.03 II B and MPEP 605.04(a) for rules governing the signatures and listing of inventors on oaths and declarations submitted for an invention.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 12-20, 24-32, and 36-39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-8 and 12 are drawn to a method for identifying statistically-outlying data points in at least one dataset.

As stated in MPEP 2106, section IV, if the claims are found to cover a judicial exception then the claims will be evaluated for providing a practical application of the judicial exception (*i.e.*, Law of Nature, Natural Phenomenon, or an Abstract Idea). This is in line with the recent decision in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008). In the instant case, the claims are drawn to an abstract idea and therefore must be evaluated further for providing a practical application of the judicial exception. Two of the possible ways for a practical application to result are: (1) if the claimed invention physically transforms an article or physical object to a different state or thing (a physical transformation), or (2) if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely provide steps of *in silico* information manipulation. Therefore, none of said steps result in a physical transformation of matter such that the whole of the claim is statutory.

As such, the claims must be further evaluated for providing the practical application. One way to do this is for the claim to produce a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case, there is no tangible result because the result is not communicated to a user. Additionally, there is no "real-world" practical application of the statistically outlying data points recited in the instant set of rejected method claims (i.e. one of skill in the art would not know what to do with the obtained data points). Consequently, the instant set of method claims lack a practical application.

However, in addition to the facts set forth above that state that a claim must provide a practical application, the claim **must also meet** the machine-or-transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008)). In other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept **may have a practical application**, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972), as clarified in *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit,

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2008) the test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus or (2) transforms a particular article to a different state or thing.

In the instant case, the method claims are not so tied to another statutory class of invention because the **method** steps that are critical to the invention are "not tied to any **particular apparatus or machine**" and therefore do not meet the machine-or-transformation test as set forth in *In re Bilski* 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008).

It is noted that claims 13-20 and 24 (software), 25-32 and 34 (storage media) and 37-39 (system), also lack a practical application for the reasons discussed above with regards to the method claims. Furthermore, claims drawn to software, per se, are not statutory (i.e. claims 13-20 and 24) because software, per se, is not statutory.

### ***Claim Rejections - 35 USC § 112***

#### **INDEFINITENESS**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 12-20, 24-32, and 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 13, 25, and 37 recite the limitation "the information" in step b of each claim. There is insufficient antecedent basis for this limitation in the claim. It is

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indefinite as to what specific information to which this information refers as the term "information" is not recited previously in the instantly rejected claims. For the purposes of examination "the information" is interpreted to be the location of each data point.

Steps d of claims 4, 16 and 28 are indefinite because it is indefinite as to the means of shifting a matrix which represents data values, by a mass (i.e. a weight). For the purposes of examination, it will be interpreted that this step comprises shifting the rows of a matrix by a constant.

Claim 37 is indefinite because of the phrasing of the steps. Claim 37 recites "a processing arrangement operably configured to... receiving .... ...identifying" wherein the first words of each of steps a and b should not be gerunds but instead verbs (i.e. to "receive" and to "identify").

Claims 5, 8, 17, 20, 29, and 32 are rejected because it is not clear from each claim in light of the specification as to what quantities the plurality of mathematical symbols represents. It is recommended that for clarity, applicant defines the variable and constants within the claim. As each of these rejected claims recites a mathematical relation as a basis, it is unclear how to fully interpret this set of claims. Consequently, for the purposes of examination it will be interpreted that claims 5, 17, and 29 represent a dataset that comprises a set of data points in real number space. Claims 8, 20 and 32 are interpreted to be the computation of a stopping point in real number space.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**35 U.S.C. 102 Rejection #1:**

Claims 1, 4-5, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Pearson [Philosophical Magazine, volume 2, 1901, pages 559-572].

Claim 1 is drawn to a process for identifying statistically outlying data points in at least one dataset, comprising:

- a) receiving the at least one dataset, and
- b) identifying the statistically-outlying data points present in that at least one dataset based on the information contained in the at least one dataset.

The article of Pearson studies regression and the fits of systems of points in space. Specifically, the figure on page 566 of Pearson illustrates the acquisition of a dataset (step a) and a use of an ellipse to statistically distinguish outlying data points within the dataset in two dimensional space (step b and preamble).

Claim 4 is further limiting comprising computing the principal axis of the at least one dataset. The figure on page 566 of Pearson illustrates the computation of the principal axis of the dataset.

With regards to claim 5, all of the data are points are in real space in the Figure on page 566 of Pearson.

Claim 37 is drawn to a system comprising a processing arrangement configured to execute the method of claim 1. The figure on page 566 of Pearson is such a processing arrangement (i.e. a display on paper).

With regards to claim 38, at least one dataset shown in the figure on page 566 of Pearson is generated.

35 U.S.C. 102 Rejection #2:

Claims 1-3 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Mutch et al. [BMC Bioinformatics, volume 3, June 2002, 11 pages, on IDS].

Claims 1 and 37 are drawn to a process for identifying statistically outlying data points in at least one dataset, as described above.

Claim 2 is further limiting wherein the at least one dataset comprises data associated with levels of expression obtained under two different conditions.

Claim 3 is further limiting wherein the conditions comprise a physiological process.

Claim 39 is further limiting comprising a detector configured to detect a plurality of signals and convert them into a data set.

The article of Mutch et al. studies a practical approach for selecting differentially expressed genes from microarray data. Specifically, the paragraph bridging pages 2 and 3 of the article describes comparison of gene expression in organs of mice.

Specifically, Figure 1b on page 4 of Mutch et al. illustrates selection of data under the two conditions of the top 1% and 10% highest fold changes of data and separates out the lower fold changes of gene expression as outliers. The paragraph bridging columns 1 and 2 of page 8 of Mutch et al. describes the instrumentation used to scan arrays to convert signals to data.

35 U.S.C. 102 Rejection #3:

Claims 1, 4-5, 13, 16-17, 25, 28-29, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. [US Patent 6,221,592; issued 24 April 2001; filed 20 October 1998].

Independent claim 1 is drawn to a process for identifying statistically outlying data points in at least one dataset, as described above.

Independent claim 13 is drawn to a software arrangement for executing the method of claim 1.

Independent claim 25 is drawn to the storage medium for executing the software of claim 13.

Independent claim 37 is drawn to a system for identifying statistically outlying data points in at least one dataset, as described above.

The patent of Schwartz et al. studies the computer-based methods and systems for sequencing of individual nucleic acid molecules. Specifically, Figure 11 of Schwartz et al. illustrates the computerized limitations of the instant set of rejected claims.

Figure 9 of Schwartz et al., as described in column 9, lines 27-28, is a variable block diagonal matrix for the dynamic programming. Column 52, lines 15-43 of Schwartz et al. describe that for data points that lie within the "dark" region of Figure 9, a conventional Gaussian function is applicable; for "white" regions that are outlying the blackened region, the special functions in Equation 8 in column 52 of Schwartz et al. need to be applied.

With regards to claims 4, 16, and 28, Figure 9 of Schwartz et al. stores the relevant data in a matrix.

With regards to claims 5, 17, and 29, Figure 9 of Schwartz et al, illustrates relevant regions in two dimensional real number space.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-8, 12, 18-20, 24, 30-32, and 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. as applied to claims 1, 4-5, 13, 16-17, 25, and 28-29 above, in further view of Beroza et al. [Journal of Computational Chemistry, volume 17, 1996, pages 1229-1244].

Claims 6-8, 12, 18-20, 24, 30-32, and 34 recite limitations with regards to computing stopping points using a top-down procedure ultimately used to define boundaries.

The patent of Schwartz et al. studies the computer-based methods and systems for sequencing of individual nucleic acid molecules, as discussed above. Schwartz et al. does not teach computing stopping points using a top-down procedure ultimately used to define boundaries between data and outlying data.

The article of Beroza et al. studies calculation of amino acid ionization constants using continuum electrostatic modeling. Specifically, Figure 2 on page 1237 of Beroza et al. illustrates an iterative top-down procedure of focusing on a portion of a protein.

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Two stopping points are shown wherein the region of the protein lying outside the matrix is considered to be outlying. The calculation of charge are continuum averages over an entire Monte Carlo simulation as taught in the title and page 1230 of Beroza et al.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the detection of outliers in Schwartz et al. by the iterative focusing and stopping of Beroza et al. wherein the motivation would have been that this top-down "zooming" provides a more detailed picture (albeit over a smaller region) of a biological process of interest. There would have been a reasonable expectation of success in applying this specific proteomic study of Beroza et al. to the more general genetic study of Schwartz et al. because the algorithm taught in Beroza et al., while specific to proteins, is a mathematical focusing algorithm generally applicable to a variety of processes, including data analysis.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RSN/  
Russell S. Negin  
21 February 2009

/Marjorie Moran/  
Supervisory Patent Examiner, Art Unit 1631